06 510(K) SUMMARY

Submitter Information

Name: Arrow International, Inc (subsidiary of Teleflex Inc.)
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Date Prepared: July 10, 2013

SEP 2 6 2013

Device Name

Device Trade Name: CG+ Arrow JACC powered by Arrow VPS Stylet
Common Name, Catheter: Central Venous Catheter
Common Name, Stylet: Catheter, Ultrasound, Intravascular

Classification Name, Catheter: Percutaneous, implanted, long-term intravascular catheter per 21 CFR: 880.5970
Classification Name, Stylet: Diagnostic Intravascular Catheter per 21 CFR 870.1200

Predicate Devices

- K103255: Vascular Positioning System (VPS System) Stylet
- K121501: Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter™ (JACC™) with Chlorag+ard® Antimicrobial and Antithrombogenic Technology

Device Description

The CG+ Arrow JACC powered by Arrow VPS Stylet has the following characteristics:

- 4.5 French, 1-Lumen, 15-35 cm pressure injectable, antimicrobial and antithrombogenic catheter preloaded with VPS Stylet
- 5.5 French, 2-Lumen, 15-35 cm pressure injectable, antimicrobial and antithrombogenic catheter preloaded with VPS Stylet
- 6 French, 3-Lumen, 15-35 cm pressure injectable, antimicrobial and antithrombogenic catheter preloaded with VPS Stylet

The CG+ Arrow JACC powered by Arrow VPS Stylet is a CG+ Arrow JACC pre-loaded with the Arrow VPS Stylet and will be provided in sterile kit configurations. The CG+ Arrow JACC devices will also be provided in sterile kit configurations without the Arrow VPS Stylet preloaded in the catheter.

The CG+ Arrow JACC is a short-term or long-term, single use catheter designed to provide access to the central venous system. It consists of a non-tapered, radiopaque polyurethane extruded catheter body with a softer, contoured Blue Flex Tip. The catheter can be used for the injection of contrast media. The maximum recommended infusion rate is 5 mL/sec for the 1-Lumen and 2-Lumen catheters and 6 mL/sec for the 3-Lumen catheter. The external catheter body and the internal fluid path of the device are treated with Chlorhexidine based coating technology.

The Arrow VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end contains a connector to the VPS Console or to an extension cable that in turn connects to the VPS Console. The stylet is designed to be compatible with any catheter with an inner luminal diameter of at least 0.021 inch.

Intended Use

The CG+ Arrow JACC powered by Arrow VPS Stylet permits venous access to the central circulation through a central vein. The VPS Stylet, used with the VPS Console, quickly and accurately guides the central catheters to the desired location which is the lower third of the SVC or at the cavo-atrial junction.

Technological Characteristics and Substantial Equivalence

The subject CG+ Arrow JACC powered by Arrow VPS Stylet is substantially equivalent to the Vascular Positioning System (VPS) Stylet (K103255) and the Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology (K121501) in terms of indications for use, manufacturing process, conditions and aids, functional performance, safety, efficacy, fundamental scientific technology and materials of construction. There is no change to the previously cleared Arrow VPS Stylet device associated with this modification. The design of the predicate Arrow Pressure Injectable Jugular Axillo-subclavian Central Catheter (JACC) with Chlorag^{+}ard Antimicrobial and Antithrombogenic Technology has been modified to create the subject device. The following table reflects a comparison of the subject and predicate device characteristics.

Subject and Predicate Device Comparison

Characteristic	Predicate: Pressure Injectable JACC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K121501)	Subject: CG+ Arrow JACC powered by Arrow VPS Stylet (Catheter Portion – CG+ Arrow JACC)
Catheter Length	20-30 cm	15-35 cm
Catheter OD	4.5 and 5.5 Fr	4.5, 5.5, and 6 Fr
Number of Lumens	1 and 2 Lumen	1,2, and 3 Lumen
Internal Lumen Configuration	1 Lumen – Round 2 Lumen - Double D	1 Lumen - Round - **SAME** 2 Lumen - Round-Crescent 3 Lumen- Round-Split-Crescent
Pressure Injection Capabilities	1 Lumen: Distal:5 mL/sec. Pressure Injectable 2 Lumen: Distal: 5 mL/sec, Pressure Injectable Proximal: 5 mL/sec, Pressure Injectable	1 Lumen: Distal:5 mL/sec. Pressure Injectable - **SAME** 2 Lumen: Distal: 5 mL/sec, Pressure Injectable - **SAME** Proximal: 4 mL/sec, Pressure Injectable 3 Lumen: Distal: 6 ml/sec, Pressure Injectable Proximal: No Pressure Injection Medial: No Pressure Injection **Note:** Lumens that are not indicated for Pressure Injection have "No CT" printed on the extension line hubs.
Catheter body material	Radiopaque polyurethane (Blue 95A/55D Tecothane with 30% Bismuth Oxychloride)	**SAME**
Catheter Juncture Hub Material	Blue Tecoflex 85A	**SAME**
Catheter Tip Design and material	Blue Flex Tip/Blue 85A Tecothane with 30% Bismuth Oxychloride	**SAME**
Extension Line Material	Clear Pellathane 90 Shore A	**SAME**
Extension Line Hub Material	Distal - Pink Isolplast >100 polyurethane Proximal – White Isoplast >100 Polyurethane	Distal - **SAME** Proximal – **SAME** Medial – Blue Isoplast >100 Polyurethane **Note:** This new material is used on the medial lumen extension line hub of the 6 Fr. catheter.
Printing Ink	2405 Black Ink	2405 Black Ink and White Ink **Note:** The white ink is used to print "No CT" on the medial lumen extension line hub of the 6 Fr. catheter.
Sterilization	1 EtO	SAME
Performance Specifications	Antimicrobial Efficacy Effective in reducing microbial colonization Antithrombogenic Efficacy Effective in reducing thrombus accumulation	SAME

<table>
<tr><th>Characteristic</th><th>Predicate: Pressure Injectable JACC with Chlorag+ard Antimicrobial and Antithrombogenic Technology (K121501)</th><th>Subject:
CG+ Arrow JACC powered by Arrow VPS Stylet
(Catheter Portion – CG+ Arrow JACC)</th></tr>
<tr><td>Content Per Surface Area</td><td>Internal: min 15 µg/cm^2
External: min 324 µg/cm^2</td><td>SAME</td></tr>
<tr><td>Chlorhexidine-based Coating - Content Per 1 cm piece of catheter</td><td>4.5 Fr. – All lengths
Internal Content: 4 – 20 µg/cm
External Content: 100-240 µg/cm
5.5 Fr. – All lengths
Internal Content: 8 – 30 µg/cm
External Content: 120 – 280 µg/cm
Extension Lines
Internal Content: 5 – 35 µg/cm</td><td>4.5 and 5.5 Fr. are the SAME

6 Fr. – All lengths
Internal Content: 13-36 µg/cm
External Content: 205-309 µg/cm

Extension Lines - SAME</td></tr>
<tr><td>Total Maximum Content of Chlorhexidine</td><td>Maximum of 22.2 mg/catheter</td><td>SAME</td></tr>
<tr><td>Formulations for Internal and External Antimicrobial Coating</td><td><table>
<tr><th>Substance</th><th>Internal Coating Concen-tration (wt %)</th><th>External Coating Concentration (wt %)</th></tr>
<tr><td>Chlorhexidine Diacetate (CHA)</td><td>1.5</td><td>2.0</td></tr>
<tr><td>Chlorhexidine Freebase (CHX)</td><td>1.5</td><td>None</td></tr>
<tr><td>Tetrahydrofuran (THF)</td><td>None</td><td>87.1</td></tr>
<tr><td>Clear 95A Tecothane polyether-polyurethane</td><td>None</td><td>6.3</td></tr>
<tr><td>Methyl Ethyl Ketone (MEK)</td><td>63.4</td><td>None</td></tr>
<tr><td>Methanol</td><td>14.5</td><td>4.6</td></tr>
<tr><td>Acetone</td><td>19.1</td><td>None</td></tr>
</table></td><td>SAME</td></tr>
<tr><th></th><th>Predicate:
Vascular Positioning System (VPS System) Stylet (K103255)</th><th>Subject:
CG+ Arrow JACC powered by Arrow VPS Stylet
(VPS Stylet Portion – Arrow VPS Stylet)</th></tr>
<tr><td>Stylet Diameter and catheter compatibility</td><td>0.019", compatible with catheters with an ID ≥ 0.021".</td><td>SAME</td></tr>
<tr><td>Stylet Length</td><td>6 Ft</td><td>SAME</td></tr>
<tr><td>Stylet Design</td><td>6 foot long polymeric tube which contains a Doppler sensor at the distal tip and Stainless Steel intravascular electrocardiogram (ivECG) signal sensing wire</td><td>SAME</td></tr>
<tr><td>Signal Conductor</td><td>Two conductor stylet wires</td><td>SAME</td></tr>
<tr><td>Sterilization</td><td>EtO</td><td>SAME</td></tr>
</table>

Nonclinical Testing

The following verification testing was performed and applies to the CG+ Arrow JACC powered by Arrow VPS Stylet:

Chlorhexidine coating testing: chlorhexidine content testing, chlorhexidine coating efficacy, chlorhexidine release rate (elution), mechanical hemolysis, solvent residual and chemical degradation.

Catheter performance testing: tensile, catheter body kink, flow rate, static burst pressure, air and liquid leakage, flex cycling, catheter whip, catheter tip compression stiffness, luer hub testing, collapse resistance and central venous pressure monitoring.

Combined device performance testing: stylet tensile, simulated use insertion/removal, force to remove stylet from catheter, and post-insertion/removal catheter air and liquid leakage and stylet electrical testing.

Conclusions

The predicate and the subject devices have the same indications for use, intended use, materials, chlorhexidine formulation, concentration (content per surface area), method of application and mechanism of release and are manufactured using the same processes, conditions and aids. The results of the risk assessment and resultant testing performed have demonstrated that the proposed design and specification changes do not raise new issues of safety or effectiveness and therefore the subject device is considered substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2013

Arrow International (Subsidiary of Teleflex Inc.)
Ms. Julie Lawson
Regulatory Affairs Specialist
2400 Bernville Road
Reading, PA 19605

Re: K132133
Trade/Device Name: CG+ Arrow JACC powered by Arrow VPS Stylet
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ LJS
Dated: August 27, 2013
Received: August 29, 2013

Dear Ms. Julie Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **CG+ Arrow JACC powered by Arrow VPS Stylet**

Indications for Use:

The Arrow® Pressure Injectable Jugular Axillo-subclavian Central Catheter™ with Chlorag+ard Antimicrobial and Antithrombogenic Technology is indicated for short-term or long-term access to the central venous system for intravenous therapy, blood sampling, infusion, pressure injection of contrast media and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the Arrow Pressure Injectable JACC™ may not exceed 300 psi. The maximum pressure injection flow rate for the specific lumen being used for pressure injection is printed on the extension line hub.

Chlorag+ard Technology treatment on the external surface of the catheter body as well as the entire fluid pathway of the catheter has been shown to be effective in reducing microbial colonization on catheter surfaces. Antimicrobial effectiveness were evaluated using *in vitro* and *in vivo* test methods and no correlation between these testing methods and clinical outcome has currently been ascertained. It is not intended to be used for the treatment of existing infections.

The VPS Stylet and Console are indicated for guidance and tip positioning for central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording and intravascular ultrasound for catheter guiding and positioning. The VPS Stylet, when used with the VPS Console, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When the VPS System guidance indicator shows a Blue Bullseye, the catheter tip is in the desired location.

The VPS System is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients when a steady Blue Bullseye is obtained. NOTE: If a steady Blue Bullseye is not obtained, standard hospital practice should be followed to confirm catheter tip location.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P-wave as in atrial fibrillation, atrial flutter, severe tachycardia and pacemaker-driven rhythm, and in central venous catheterization procedures performed through femoral or saphenous vein access which change the presentation of the P-wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.09.26 14:49:51 -04'00'